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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,775	10/07/2005	Masayoshi Yamaguchi	4532660/55140	5188

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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12/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,775	Applicant(s) YAMAGUCHI, MASAYOSHI	
	Examiner Raymond J. Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7,8,15 and 17 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7,8,15 and 17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date <u>2 sheets</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: ____.</p> |
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CLAIMS 1, 3, 4, 7, 8, 15 AND 17 ARE PRESENTED FOR EXAMINATION

Applicant's Preliminary Amendment filed April 22, 2005 and Information Disclosure Statements filed April 20, 2006 and November 7, 2006 have been received and entered into the application.

The claims have been amended as indicated by Applicant. Also, as reflected by the attached, completed copies of form PTO/SB/08, (2 sheets), the submitted references have been considered.

Claim Rejections - 35 USC § 112, (First Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

I Claims 4, 8 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating bone diseases, such as osteoporosis, does not reasonably provide enablement for the prevention of the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use, with a reasonable degree of success, the invention commensurate in scope with these claims.

Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective*

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truth of statements contain therein which must be relied on for enabling support; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Here, the objective truth of the statement that bone diseases, such as osteoporosis, disease can be prevented is doubted the term “preventing” is synonymous with the term “curing”, (see MPEP § 2111 regarding broad and reasonable claim interpretation), and both circumscribe methods of absolute success. Because absolute success is not reasonably possible with most diseases/disorders, the specification, which lacks an objective showing that osteoporosis can actually be prevented, i.e., kept from every occurring to any degree, is viewed as lacking an enabling disclosure of the same.

Further supporting the Examiner's doubt is the state of the art and Applicants' present specification. With respect to the latter, the present specification contains no actual clinical data showing that osteoporosis can be prevented. It is fully recognized that actual working examples are not necessary, in and of themselves, to enable an invention. However, such *is* a factor to be considered in evaluating whether or not an invention is enabled, (i.e., see *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988), specifically “factor 5” therein which is the presence or absence of working examples in Applicants' specification. Respecting the former, which in *Wands, Id.*, is referred to as “factor 2”, i.e., state of the art, the art appears to indicate that while successful treatments of osteoporosis, including treatment with bisphosphonate compounds, have been realized and accepted, such is not the case with the prevention or cure of such. In support of the Examiner's position here, the following teachings are relied on:

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(i) Johansen et al., (abstract of a Drugs & Aging article, cited by the Examiner), teaches “Bisphosphonates *show promise* in the prevention and treatment of osteoporosis and increase bone mass in postmenopausal and steroid-induced osteoporosis”, (emphasis added, penultimate sentence);

(ii) Frost, (abstract of a Medicina article, cited by the Examiner), teaches “Controlling existing osteoblasts and osteoclasts with drugs¹ *has not prevented or cured* [four osteopenias included in the term osteoporosis]”, (emphasis added, middle of the abstract), and “Combining anabolic agents with remodeling agents offers an *exceptionally promising prospect of effective prevention and cure* of the above osteopenias”, (emphasis added, penultimate sentence); and

(iii) Boyle, (abstract of a Bailliere’s Clinical Rheumatology article, cited by the Examiner), teaches “Even in steroid-induced osteoporosis, one of the commonest and most severe forms of osteoporosis, we now have some effective therapy in the form of the bisphosphonates and other anti-bone-resorbing drug classes. The *possibility of prophylaxis* against secondary osteoporosis has therefore *become a possibility, although the very long-term effects of such drug regimens are still unknown*”, (emphasis added, three-quarters way down in the abstract).

Thus, because of the above reasons, the Examiner doubts the objective truth of the statement that the presently claimed combination of active agents will prevent osteoporosis and/or Paget’s disease and the Examiner has therefore satisfied the burden as set forth in *In re Marzocchi, Id.* for making a rejection under 35 U.S.C. § 112, first paragraph. Also, because the art has not recognized successful treatments which actually prevent and/or cure osteoporosis, the

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actual accomplishment of such prevention and/or cure would not be viewed as predictable to one skilled in the art. Accordingly, the claims are deemed properly rejected.

Applicants may wish to consider deleting "or preventing" in the claims in order to overcome the present ground of rejection.

II Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the manner in which the artisan is to identify a candidate compound or a population of candidate compounds, from all known compounds, for assaying in a manner as claimed has not been adequately described such that the artisan could practice the present invention without an undue amount of experimentation.

While it is noted that the present disclosure describes a method for performing "assays" in order to discover compounds having the capability of promoting osteogenesis or treating bone diseases, the disclosure does not furnish sufficient guidance or direction in selecting a population of compounds to test, i.e., candidate compounds, or provide information that would narrow the astronomical range of possible candidate compounds known to the skilled artisan. Thus, one skilled in the art would have to engage in undue experimentation in order to determine which compounds, from the vast number of compounds known, would be suitable for testing and even then would have no assurance that the claimed objectives could be practiced.

The present disclosure does no more than describe the desired or target function of the compounds being sought, i.e., compounds which have the capability of promoting osteogenesis or treating bone diseases.

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At best, the disclosure simply indicates that one should run tests on an infinite number of compounds in the hope that at least one of them will work. The disclosure where it is indicated what "candidate compounds" means is nebulous, *e.g.*, " β -cryptoxanthin is used as the lead compound, (claim 15). Nowhere does the disclosure specify which population of compounds should be first subjected to testing. Also, nowhere is it found that Applicant provides an adequate means of determining a population of suitable candidate compounds from the universe of known compounds, which determination would be necessary in order to practice the claimed methods. That is, there is no indication that the inventor has actually identified any particular compound.

In the specification as filed, there does not appear that the inventors have identified so much as one compound that would be suitable for use in practicing the claimed invention. Lacking such an identification by the inventors themselves, it is not seen that another party, *i.e.*, the skilled artisan, could be lead in any manner so as to do that which the inventors themselves have not done, *i.e.*, identify a candidate compound necessary to practice the invention. The disclosure should be a description of an invention and not an indication of a result that one - might achieve if one were to make that invention. The present disclosure is not seen to do any more than outline the goals which the inventors hope to achieve and the problems that the invention will hopefully ameliorate. This, however, does not satisfy the written description or enablement requirement under 35 U.S.C. § 112, first paragraph. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003).

Claim Rejection - 35 USC § 112, (Second Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.", (see MPEP § 2173).

In claim 15, the phrase "is used as the lead compound" fails to make clear the metes and bounds of the subject matter for which Applicant seeks patent protection.

Claim Rejection - 35 USC § 102(a)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 3, 4, 7, 8 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Applicants' acknowledgment at page 3 of the present specification, lines 10-26.

The present claims read on a simple composition comprising β -cryptoxanthin, such as a food. In Applicants' specification, such composition is disclosed as known. The mere recitation of a use for the composition not previously known does not create a new compound or

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composition. The physical characteristics of the composition would remain the same. Thus, Applicant's claims fail to define a composition that is new.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/
Primary Examiner
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October 27, 2008